

K030883 1/2

JUN 18 2003

**510(k) Summary of Safety and Effectiveness for the  
Photo Therapeutics Limited Omnilux Blue**

This 510(k) Summary of Safety and Effectiveness is being submitted in accordance with the requirements of the SMDA 1990 and 21 CFR 807.92.

**1. General Information**

Submitter:

Photo Therapeutics Limited  
Station House  
Stamford New Road  
Altrincham  
Cheshire WA14 1EP  
United Kingdom

Contact Person:

Maureen O'Connell  
5 Timber Lane  
North Reading, MA 01864  
Telephone: 978-207-1245  
Fax: 978-207-1246

Summary Preparation Date:

March 18, 2003

**2. Names**

Device Name:

Omnilux Blue

Classification Name:

Laser Instrument, Surgical Powered  
Product Code: GEX  
Panel: 79

**3. Predicate Devices**

The Omnilux Blue is substantially equivalent to the Lumenis Clearlight (K013623).

**4. Device Description**

The Omnilux Blue is a visible light source of high spectral purity. It provides uniform or "hot-spot" free illumination. The output is pre-tuned to one wavelength with a narrow spectral bandwidth. The output wavelength is  $415 \pm 5$  nm. The Omnilux Blue base unit contains the power supplies and the control unit. Attached to the base unit are three folding arms. The LED head can be attached to the end of the arms and then positioned for patient treatment. The control unit consists of an LCD and keyboard together with

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the control electronics. The user interface software allows the operator to access and control all device functions.

**5. Indications for Use**

The Omnilux Blue which is generally indicated to treat dermatological conditions and specifically indicated to treat moderate inflammatory acne vulgaris.

**6. Performance Data**

Based upon an analysis of the overall performance characteristics for the device, Photo Therapeutics Limited believes that no significant differences exist. Therefore, the Omnilux Blue raises no new issues of safety or effectiveness.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

JUN 18 2003

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Photo Therapeutics Limited  
c/o Ms. Maureen O'Connell  
Regulatory Consultant  
5 Timber Lane  
North Reading, Massachusetts 01864

Re: K030883

Trade/Device Name: Omnilux Blue  
Regulation Number: 21 CFR 878.4810  
Regulation Name: Laser surgical instrument for use in general  
and plastic surgery and in dermatology  
Regulatory Class: II  
Product Code: GEX  
Dated: March 19, 2003  
Received: March 20, 2003

Dear Ms. O'Connell:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

*Miriam E. Provost*  
for Celia M. Witten, Ph.D., M.D.  
Director  
Division of General, Restorative  
and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

K030883

510(k) Number (if known)

Device Name Omnilux Blue

**Indications for Use:**

The Omnilux Blue is generally indicated to treat dermatological conditions and specifically indicated to treat moderate inflammatory acne vulgaris.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X  
(Per 21 CFR 801.109)

OR

Over The Counter Use \_\_\_\_\_

Miriam C. Provost  
(Division Sign-Off) (Optional Format 1-2-96)  
Division of General, Restorative  
and Neurological Devices

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